EXHIBIT B

ORIGINAL

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO
CIVIL DIVISION

JENNY GRIMM
134 Garvey Ave.
Elsmere, KY 41018

Plaintiff,

v.

ABUBAKAR ATIQ DURRANI, M.D.,
(Pakistan)
(Serve via Hague Convention)

And

CENTER FOR ADVANCED SPINE TECHNOLOGIES, INC.
(Serve via Hague Convention)

And

WEST CHESTER HOSPITAL, LLC
7700 University Drive
West Chester, OH 45069

Serve: GH&R Business Svcs., INC.
511 Walnut Street
1900 Fifth Third Center
Cincinnati, OH 45202
(Serve via Certified mail)

REGULAR MAIL WAIVER

And

UC HEALTH
Serve: GH& R BUSINESS SVCS., INC.
511 WALNUT STREET
1900 FIFTH THIRD CENTER
CINCINNATI, OH 45202
(Serve via Certified Mail)

REGULAR MAIL WAIVER

Defendants.

Case No. A 1506165

Judge:

COMPLAINT & JURY DEMAND

(ALL NEW DR. DURRANI CASES SHALL GO TO JUDGE RUEHLMAN PER HIS ORDER)

FILED
2015 NOV 12 A 9:53
TRACY WILLER
CLERK OF COURTS
HAMILTON COUNTY, OH

D112574130 INI

Comes now Plaintiff, Jenny Grimm, and files this Complaint and jury demand, stating as follows:

1. At all times relevant, Plaintiff was a resident of and domiciled in the State of Kentucky.

2. At all times relevant, Defendant Dr. Abubakar Atiq Durrani (hereinafter "Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.

3. At all times relevant Dr. Durrani was an employee of West Chester/ UC hospital.

4. At all times relevant, West Chester Hospital, LLC (hereinafter "West Chester Hospital"), was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operate under the trade name West Chester Hospital.

5. At all times relevant, Defendant UC Health Inc., was a duly licensed corporation which owned, operated and/or managed multiple hospitals including, but not limited to West Chester Hospital, and which shared certain services, profits, and liabilities of hospitals including West Chester.

6. At all times relevant herein, West Chester Medical Center, Inc., aka West Chester Hospital held itself out to the public, and specifically to Plaintiffs, as a hospital providing competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.

7. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC.

8. UC Health Stored BMP-2 at UC Health Business Center warehouse located in Hamilton County.

9. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC. UC Health is located in Hamilton County making Hamilton County appropriate to bring this lawsuit.

10. The amount in controversy exceeds the jurisdictional threshold of this Court.

11. The subject matter of the Complaint arises out of medical treatment by Defendants in Hamilton County, Ohio. This Court is thus the proper venue to grant Plaintiff the relief sought.

12. This case has been previously 41(A) voluntarily dismissed and now is being re-filed.

FACTUAL ALLEGATIONS OF PLAINTIFF

13. Plaintiff began treatment with Dr. Durrani on August 6, 2009 for lower and mid back pain. Dr. Durrani informed Plaintiff on the first visit she would need cervical surgery, even though radiology reports show no medical problems at C6-C7.

14. On or about September 30, 2009 Dr. Durrani performed a C5-C6, C6-C7 anterior cervical discectomy, C5-C6, C6-C7 anterior spinal fusion surgery on Plaintiff at West Chester Hospital/UC Health installing hardware.

15. Immediately following the surgery, Plaintiff began suffering extreme headaches, neck pain, bilateral arm and leg pain, neck swelling, restricted breathing and paralysis and numbness in both hands and legs.

16. When Plaintiff informed Dr. Durrani of these symptoms, he recommended a second surgery to correct a bulging disc in her back.

17. On or about January 18, 2010 Dr. Durrani performed surgery on Plaintiff at West Chester Hospital/UC Health. He informed her this would bring immediate relief.

18. Dr. Durrani performed a L3- L4 direct lumbar interbody fusion using autograft and allograft, placement of a lumbar cage, a posterior spinal instrumentation with Facet Screws and posterior spinal fusion using auto and allograft L3-L4.

19. During the surgery Dr. Durrani and his surgical team collapsed Plaintiff's lung and installed a chest tube. This caused massive scarring and permanent lung impairment.

20. Plaintiff continued to follow up with Dr. Durrani and informed him she now had worsened symptoms. Dr. Durrani recommended a third surgery by saying "I can fix you this time."

21. Plaintiff sought a second opinion from Dr. Karakpaludi at Commonwealth Orthopedic Center who informed her the surgeries were unnecessary.

22. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" without Plaintiff's knowledge or consent, in one or more surgeries causing harm.

23. Upon information and belief, during this surgery, Dr. Durrani used Infuse/BMP-2 and/or Puregen, without Mrs. Jone's knowledge or consent, causing Ms. Jones harm.

24. The use of BMP-2 increases a person's chance of cancer by 3.5%

25. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

26. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result Plaintiff has an increased fear of Cancer.

27. Upon information and belief, the surgeries upon Ms. Grimm by Dr. Durrani were medically unnecessary.

28. As a result of the negligence of the Defendants named herein, Ms. Grimm has

suffered damages including medical expenses, pain and suffering and loss of enjoyment of life.

29. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' medical records.

MORE SPECIFIC ALLEGATIONS BASED UPON DISCOVERY AND DEPOSITION TESTIMONY

30. This information is to demonstrate the overall negligence and inappropriate actions of Dr. Durrani and the hospitals he worked with and/or for and/or in an individual capacity.

31. Krissy Probst was Dr. Durrani's professional and personal assistant handling professional, academic, travel, surgery scheduling, his journals, his Boards, his credentialing, his personal affairs and his bills.

32. Krissy Probst worked as Dr. Durrani's assistant for three years at Children's Hospital from 2006, 2007, and 2008.

33. Krissy Probst reported Dr. Durrani to Sandy Singleton, the Business Director at Children's for his having an affair with Jamie Moor, his physician assistant.

34. Krissy Probst resigned in 2008 from Dr. Durrani and remained working for three other surgeons in the Orthopedic Department.

35. Krissy Probst worked in the Orthopedic Department for eleven years from 2002-2013. She retired in May, 2013.

36. Krissy Probst confirmed Dr. Durrani claims being a Prince, when he is not.

37. According to Krissy Probst, Dr. Crawford, an icon in pediatric orthopedics treated Dr. Durrani "like a son."

38. According to Krissy Probst, Dr. Crawford, Chief of Orthopedics at Children's unconditionally supported Dr. Durrani no matter the issues and problems Dr. Durrani faced.

39. Dr. Durrani's patient care at Children's Hospital dropped off considerably after Jamie Moor became his physician assistant and they began their affair.

40. Dr. Durrani was the only orthopedic spine surgeon at Children's who would perform a dangerous high volume of surgeries.

41. At Children's, Dr. Durrani would begin a surgery, leave and have fellows and residents complete a surgery or do the full surgery while he was in his office with Jamie Moor, his physician assistant for four or five hours.

42. Children's Board and administration knew about Dr. Durrani doing too many surgeries and not properly doing the surgeries. They did nothing.

43. Dr. Durrani argued to Children's administration when they complained to him that he made them money so Children's tolerated him and allowed him to do what he wanted.

44. Dr. Durrani, when told by Children's that Jamie Moor had to leave, told Children's that he would leave too.

45. Dr. Agabagi would do one spine patient a day at Children's because it takes normally eight hours for a full fusion.

46. Dr. Durrani would schedule two to three spine surgeries a day at Children's.

47. Dr. Durrani would repeatedly have the Business Director, Sandy Singleton, or OR Director allow him to add surgeries claiming they were emergencies when they were not.

48. Dr. Durrani would leave a spine surgery patient for four or five hours in the surgery suite under the care of fellows or residents, unsupervised and sit in his office and check on the surgery as he pleased.

49. Dr. Peter Stern did not like Dr. Durrani while Dr. Durrani was at Children's because he knew all about his patient safety risk issues. Yet, Dr. Stern supported, aided and abetted Dr. Durrani's arrival at West Chester. It defies comprehension, but was for one of the world's oldest motives—greed of money.

50. There is also a Dr. Peter Sturm, an orthopedic at Children's who also had no use for Dr. Durrani.

51. Dr. Durrani chose his own codes for Children's billing which he manipulated with the full knowledge of Children's Board and management.

52. Dr. Durrani was dating and living with Beth Garrett, a nursing school drop-out, with the full knowledge of his wife Shazia.

53. Dr. Durrani was close with David Rattigan until David Rattigan pursued Jamie Moor and Dr. Durrani would not allow David Rattigan in the OR at Children's for a long time.

54. Dr. Durrani, while claiming to have riches, does not. Dr. Durrani's wife's family paid for Dr. Durrani's education and it is her family with the significant wealth.

55. Medtronics paid for Dr. Durrani's trips and paid him $10,000 fees for speaking or simply showing up at a spine conference.

56. Krissy Probst's business director told her to save all Dr. Durrani related documents and information and she did.

57. While doing research at Children's, Dr. Durrani would misstate facts regarding his research. Children's knew he did this.

58. Dr. Durrani ended on such bad terms with Children's Hospital he was not allowed on the premises after his departure in December 2008, yet he performed a spine surgery there in February 2009.

59. Eric J. Wall, MD was the Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

60. Sandy Singleton, MBA was the Senior Business Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

61. On information and belief, Dr. Durrani used his relationships with Children's officials to purge his Children's file of all patient safety and legal issues which had occurred as part of his departure "deal" which Defendants hide with privilege.

INFUSE/BMP-2

I. BACKGROUND INFORMATION

62. The Deters Law Firm, P.S.C., represents approximately 500 Plaintiffs in medical malpractice actions against a former Northern Kentucky/Cincinnati-area spine surgeon named Abubakar Atiq Dr. Durrani (Dr. Durrani), his company, Center for Advanced Spine Technologies, Inc. (CAST), and several area hospitals including, but not limited to, West Chester Hospital (WCH), University of Cincinnati Health (UC Health), Cincinnati Children's Hospital Medical Center (CCHMC), Christ Hospital, Deaconess Hospital, Good Samaritan Hospital and Journey Lite of Cincinnati, LLC (Journey Lite) (collectively Hospitals).

63. Dr. Durrani performed unnecessary, fraudulent, dangerous, and ultimately damaging surgeries on these Plaintiffs while working for and with these Hospitals.

64. The scheme and artifice to defraud that Dr. Durrani devised, executed, and attempted to execute while working for and with the Hospitals included the following patterns and practices:

a. Dr. Durrani persuaded the patient that surgery was the only option, when in fact the patient did not need surgery.

b. Dr. Durrani told the patient that the medical situation was urgent and required immediate surgery. He also falsely told the patient that he/she was at risk of grave injuries without the surgery.

c. Dr. Durrani often told his cervical spine patients that they risked paralysis or that his/her head would fall off if he/she was involved in a car accident, ostensibly because there was almost nothing attaching the head to the patient's body.

d. Dr. Durrani often ordered imaging studies such as x-rays, CT scans, or MRIs for patients but either did not read or ignored the resulting radiology reports.

e. Dr. Durrani often provided his own exaggerated and dire reading of the patient's imaging study that was either inconsistent with or was plainly contradicted by the radiologist's report. At times, Dr. Durrani provided a false reading of the imaging.

f. Dr. Durrani often dictated that he had performed certain physical examinations and procedures on patients that he did not actually perform.

g. Dr. Durrani often ordered a pain injection for a level of the spine that was inconsistent with the pain stated by the patient or with that indicated by the imaging. Dr. Durrani also scheduled patients for surgeries without learning of or waiting for the results of certain pain injections or related therapies.

h. Dr. Durrani often dictated his operative reports or other patient records months after the actual treatment had occurred.

i. Dr. Durrani's operative reports and treatment records contained false statements about the patient's diagnosis, the procedure performed, and the instrumentation used in the procedure.

j. When a patient experienced complications resulting from the surgery, Dr. Durrani at times failed to inform the patient of, or misrepresented the nature of, the complications.

k. All of the above-mentioned actions were done with the knowledge, cooperation, or intentional ignorance of the Hospitals because Dr. Durrani was one of the biggest moneymakers for the Hospitals.

65. In addition to the civil medical malpractice actions against Dr. Durrani, on August 7, 2013, he was indicted by the Federal Government for performing unnecessary surgeries and for defrauding the Medicare and Medicaid programs. Specifically, the ten-count complaint charged Dr. Durrani with health care fraud, in violation of 18 U.S.C. § 1347, and making false statements in health care matters, in violation of 18 U.S.C. § 1035. There was a subsequent superseding indictment adding over 30 counts.

66. Following these criminal indictments, in December of 2013 and prior to the first Plaintiff's trial in these actions, Dr. Durrani fled the United States and returned to

Pakistan. He has not returned to the United States to face allegations of either criminal or civil liability.

67. Among Dr. Durrani's and the Hospitals' professional failings was the use of a synthetic bone-morphogenetic protein called BMP-2, which was marketed under the trade name "Infuse." Dr. Durrani used BMP-2/Infuse in ways that were either not approved by the federal Food and Drug Administration (FDA) or that were specifically contraindicated as noted on the FDA-approved product labeling. The Defendants had full knowledge of this fact.

68. BMP-2/Infuse was, at the time of the surgeries in question, and currently still is manufactured by a company called Medtronic, Inc. (Medtronic).

69. Dr. Durrani predominantly used BMP-2/Infuse on patients at WCH, which is owned by UC Health.

70. It is Plaintiffs' position that this non-FDA-approved use of BMP-2/Infuse was not only negligent, and fraudulent, but criminal based upon the manner in which it was allowed to be used by Dr. Durrani at West Chester, all with the knowledge and full support of the Defendants.

II. THE PLAYERS REGARDING BMP-2

71. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.

72. Medtronic is an Irish corporation, with its principal executive office located in Dublin, Ireland, and its operational headquarters located in Minneapolis, Minnesota. Medtronic is

the world's third largest medical device company and manufactures and markets BMP-2/Infuse. Medtronic sales representatives were also present during the experimental surgeries performed on Plaintiffs, who are clients of the Deters Law Firm.

73. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.

74. Bahler Medical, Inc. is a manufacturer of medical implants and is a corporation located in the state of Ohio.

75. David Rattigan is an Ohio resident and was and is a sales representative for Medtronic. Further, he is affiliated with Bahler Medical, Inc., was involved in many of the transactions involving BMP-2, and was present for the experimental surgeries in which BMP-2 was used.

76. West Chester Hospital, LLC is a corporation organized under the laws of Ohio. It provides medical facilities and billing support to physicians, including Dr. Durrani, in the state of Ohio. WCH is owned by UC Health.

77. UC Health is a private, non-profit corporation organized under the laws of Ohio. It provides medical facilities, management, administrative, ancillary, and billing support to physicians, and it owns WCH.

78. CCHMC is a medical facility in Ohio where Dr. Durrani was an employee until approximately 2008.

III. WHAT IS BMP-2/INFUSE?

79. The full name of BMP-2 is "Recombinant Human Morphogenetic Protein-2" (also called rhBMP-2). The following definitions apply:

a. Recombinant – Artificially created in a lab;

b. Morphogenetic – Evolutionary development of an organism;

c. Protein – Essential for growth and repair of tissue.

80. Recombinant human protein (rhBMP-2) is currently available for orthopedic usage in the United States.

81. Medtronic manufactured, marketed, sold, and distributed BMP-2 under the trade name "Infuse."

82. BMP-2 has been shown to stimulate the production of bone.

83. Implantation of BMP-2 in a collagen sponge induces new bone formation and can be used for the treatment of bony defects, delayed union, and non-union.

BMP-2 AS A BIOLOGIC

84. BMP-2 is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.

85. According to the FDA, "[a] 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service ActSec.351(i)1."Available http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

86. BMP-2 is a Bone-Morphogenetic Protein that is used to promote bone creation and remolding and falls under the definition of a biologic. *See* AMA article ("bone forming properties") and Stanford Article. BMP-2 differs from a medical device in that once implanted, it can only be removed days after surgery. If a patient had a complication due

to BMP-2 and did not discover this complication until year after surgery, the patient could not have BMP-2 removed to reduce the complication because BMP-2 is so integrated into the patient's bone.

87. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

WHEN IS IT USED?

88. Recombinant human BMPs are used in orthopedic applications such as spinal fusions, non-unions, and oral surgery.

89. The bone graft contains two parts. The first is a solution of human bone growth protein or morphogenetic protein-2. This protein is found in the human body in small dosages and is important for the healing and formation of bones. The protein is genetically engineered to be utilized in the Infuse Bone Graft product, and it is employed for the stimulation of formation and growth in bones.

90. The second part of the bone graft is an absorbable collagen sponge.

91. Both components of the Infuse Bone Graft structure are used to fill the LT-Cage Lumbar Tapered Fusion Device. This chamber is intended to restore the deteriorated disc space to its original height.

92. FDA-approved use for the Infuse Bone Graft product is only for lower back surgery using an anterior lumbar interbody fusion (ALIF), a technique where the operation on the spine is conducted through the abdomen.

93. In addition, the Infuse Bone Graft product must be used in conjunction with Medtronic's LT-Cage. Use of BMP-2 without the LT-Cage is considered an "off-label" use.

CONTRAINDICATIONS OF USE

94. The FDA specifically warns against the use of Infuse in the cervical spine, citing reports of "life-threatening complications."

95. Any use of Infuse other than in lumbar spine surgeries with the LT-Cage is considered "off-label" use

96. Infuse should never be used on the skeletally immature patient, i.e., in patients less than 18 years of age or those with no radiographic evidence of epiphyseal closure.

97. Infuse should never be used in the vicinity of a resected or extant tumor.

98. Infuse should never be used in those patients known to have active infection at the surgical site.

RISKS ASSOCIATED WITH OFF-LABEL USE

99. When used in an off-label manner, patients may experience problems with pregnancy, including but not limited to: complications in fetal development; allergic reactions to titanium, bovine type I collagen, or bone morphogenetic protein–2; infection; the creation or intensification of tumors; liver or kidney disease; lupus or human immunodeficiency virus (HIV/AIDS); problems with radiation, chemotherapy, or steroids if a patient is malignant; paralysis; bowel and/or bladder dysfunctions; sexual disorders, including sterilization and incompetence; respiratory failure; excessive bleeding, and; death.

IV. THE REGULATORY PROCESS

100. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., established two separate approval processes for medical devices: Pre–Market Approval (PMA) and Pre–Market Notification.[1]

101. The FDA's PMA process is lengthy and involves extensive investigation by the FDA. The PMA application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require PMA applicants to submit copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(10). The FDA approves a PMA application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.[2]

102. In contrast, the FDA's Pre–Market Notification process is more abbreviated and involves less FDA oversight. This process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. Pre–Market Notification applicants must also submit their proposed labeling. 21 C.F.R. § 807.87. If the FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDA in 1976, the applicant is free to market the device.

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[1] *Fender v. Medtronic,* 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

[2] *Fender v. Medtronic,* 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

103. BMP-2 received PMA (PMA number P000058) for the Infuse/BMP-2 Lumbar Tapered Fusion Device, which PMA provided for limited use with specific requirements for its use on individuals. See Medtronic Package Insert.

SCOPE OF THE PMA AND PRODUCT LABELING

104. The PMA for BMP-2 provided that the product may only be used in patients with the following characteristics:

d. Skeletally mature patient, AND

e. At levels L2-S1, AND

f. Confirmed degenerative disc disease (DDD), AND

g. Using only an open anterior or anterior laparoscopic approach, AND[3]

h. Six months of non-operative treatment prior to treatment with the device, AND

i. In combination with the metallic LT-CAGE.[4]

See Medtronic Package Insert, "INDICATIONS."

105. According to Medtronic's package insert for BMP-2/Infuse as well as other industry literature, the following risks are associated with the use of BMP-2/Infuse:

A. Male Sterility

B. Cancer

C. Increased progression of cancer

D. Suffocation of the cervical region

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[3] The anterior interbody fusion approach was developed because the risk of non-union (pseudarthrosis) is significantly higher in posterior approaches. The biggest risk factor for fusion surgery is non-union.

[4] Instrumented fusions involve hardware and are more stable fusions with a shorter recovery time than non-instrumented fusions.

E. Bone fracture

F. Bowel/bladder problems

G. Loss of spinal mobility or function

H. Change in mental status

I. Damage to blood vessels and cardiovascular system compromise

J. Excessive bone mass blocking the ability to treat pain

K. Damage to internal organs and connective tissue

L. Death

M. Respiratory problems

N. Disassembly and migration of components

O. Dural tears

P. Ectopic and exuberant bone formation

Q. Fetal development complications (birth defects)

R. Foreign body (allergic) reaction

S. Gastrointestinal complications

T. Incisional complications

U. Infection

V. Insufflation complications

W. Neurological system compromise

X. Non-union

Y. Delayed union

Z. Mal-union

AA. Change in curvature of spine

BB. Retrograde ejaculation

CC. Scars

DD. Tissue and nerve damage

EE. Itching

FF. Pain

GG. Hematoma

HH. Anaphylactic reaction

II. Elevated erythrocyte sedimentation rate

106. Injury Percentages:

j. Ectopic Bone Growth-63%

k. Inflammatory Neuritis-15%

l. Osteolysis/Subsidence-13%

m. Acute Swelling-7%

n. Retrograde Ejaculation-2%

o. 85% of time, BMP-2 implanted in off-label use

107. Not a single one of these risks in the last two paragraphs were ever explained to a single patient at Children's Hospital by Dr. Durrani.

108. BMP-2 was NOT approved by the FDA for use in the cervical and thoracic spine and BMP-2 was NOT safe or approved for use in children less than 21 years of age. These uses are considered "off-label."

"OFF-LABEL" USE

109. A use of a device is considered "off-label" if it is not approved under the Pre-Market Approval process OR cleared for such use pursuant to 21 U.S.C. § 360c(f) (also known as "the 510k premarket notification process").

110. Infuse can be implanted in an off-label manner in three ways:

p. Approach/position: Any approach other than an anterior approach;

q. Product: Failure to use LT-Cage (or any cage); mixing rhBMP-2 with other grafting products like Allograft or Autograft;

r. Discs: Use on multiple levels or on a level outside of L2-S1.

111. Dr. Durrani and the Hospitals in which he performed surgeries repeatedly used BMP-2 in these non-FDA-approved manners.

THE NON-COMPLIANCE WITH THE REGULATORY PROCESS

112. The PMA 000058 "Conditions of Approval" specifies the following condition: "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by the FDA ... [a] PMA supplement or alternate submission shall comply with applicable requirements under 21 C.F.R. 814.39[.]"

113. 21 C.F.R. 814.39 requires a PMA supplement pursuant to subsection (a)(1) for new indications of use of the device and pursuant to subsection (a)(6) for changes in components.

114. The PMA 000058 "Conditions of Approval" notes the post-marketing reporting requirement imposed by 21 C.F.R. 814.84, particularly "Identification of changes described in 21 C.F.R. 814.39(a)." Medtronic did not comply with this requirement relating to the intended uses and componentry.

115. The FDA can impose post-approval requirements in the PMA pursuant to 21 C.F.R. 814.82, and this fact results in the device being characterized as "restricted" pursuant to 21 U.S.C. § 360j(e) for purposes of 21 U.S.C. § 352(q). Section 352(q) states that any restricted device that is distributed or offered for sale with false or misleading advertising is "misbranded."

116. "Indications for use" is a necessary part of the PMA application and the "Indications for use" are required to be limited by the application. Any different use is inconsistent with the PMA.

117. A device that fails to meet the requirements of the PMA or 21 C.F.R. 814 is "adulterated" as defined by 21 U.S.C. § 351(f).

118. 21 C.F.R. 801.6 *defines a misleading statement related to a* DIFFERENT *device* contained in the label delivered with the device intended to be used will render the device to be used misbranded.

119. Medtronic did not apply for a PMA supplement, as required by the FDA generally and PMA 000058 specifically, for the off-label uses, nor did it provide warnings of the risks known about the off-label uses. All named Defendants in these cases knew about the occurrences of off-label use.

120. The PMA requires an application prior to marketing for new indicated uses by incorporating the federal requirements and explicitly reciting the text of 21 C.F.R. 814.39 and 814.84 and by specifically stating the range of indicated uses on the PMA.

V. MEDTRONIC

121. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products, PYRAMID and INFUSE (BMP-2), which it projected would enjoy broad application with spinal surgeons and their patients on a nationwide basis.

122. Medtronic anticipated that both products would initially be limited in application.

123. Motivated by greed and a desire to gain competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end-users. The course of conduct involved fraud, false statements, material misrepresentation, and deceit for the purpose of broadening the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

124. On or after July 2, 2002, Medtronic received notification that its Pre-Market Approval application for its BMP-2/Infuse bone graft products had been approved by the FDA. However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate the long-term performance of the BMP-2 bone graft and to study the potential side effects and complications such as the promotion of tumors by the bone morphogenetic protein component of BMP-2. Other studies were conducted as well. See "Allegations against Medtronic in the Unsealed Mississippi False Claims Case."

125. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from BMP-2, regardless of whether it would eventually be allowed to remain on the market.

126. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-Cage, was the only approved device to act as the delivery vehicle for BMP-2 into the body.

127. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and he was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

128. In one of Dr. Zdeblick's first attempts to tout his LT-Cage and rhBMP-2, which would become the active ingredient in the ultimate Infuse/BMP-2 product, he encountered some drawbacks to his goal of promoting his and Medtronic's products, which arose from the policy of certain industry journals, including the journal *Spine,* which followed industry standards before printing peer-reviewed material. See article in the journal *Spine,* published in 2000.

129. Not only were the drawbacks related to industry publishing standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain provisions at 42 U.S.C. § 300u, et seq., whereby the Federal Government had entered the field of medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services required that applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. § 300u-1.

130. The drawbacks encountered with the peer-reviewed *Spine* article were as follows:

a. Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc.;"

b. The study was conducted under FDA regulations, and was "...designed as a prospective, multicenter, nonblinded, randomized, and controlled pilot study;" and

c. It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article.

131. In the article, BMP-2 was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, where it closed with the following: "...it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition."

132. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that, "[p]erhaps vascularization...fixation procedures are as important as the biochemical composition of the 'filler.'"

133. Vascularization is achieved through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other, if the alternative proposed by Dr. O'Brien proved to achieve equivalent or better results, Zdeblick and Medtronic's Infuse/BMP-2 products would be useless and unnecessary.

134. Certain efforts would follow in an attempt to alleviate the drawbacks encountered with the 2000 *Spine* journal article.

135. In 2002, Dr. Zdeblick was installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the journal enjoyed a fourteen year history under the co-editorship of Dr. Dan Spangler and

Dr. Tom Ducker. Once installed, Dr. Zdeblick successfully supplanted Drs. Dan Spengler and Tom Ducker and became the sole editor-in-chief, a position which would enable him to have greater control and would aid his participation in the fraudulent scheme.

136. During this same time period, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

137. In one of Dr. Zdeblick's actions as editor-in-chief, he set about re-purposing the journal in a way that would aid him in the furtherance of the fraudulent scheme through the streamlining of the publication process.

138. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques* (JSDT), announcing that the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice.

139. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques...", and in furtherance of that goal, Dr. Zdeblick announced that his journal would publish Class II or better clinical articles but would "occasionally accept cutting edge articles with less than one year follow-up." To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his journal "to keep up with the fast pace of progress in the treatment of spinal patients."

140. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of JSDT.

141. In the October 2002 edition, JSDT published an article entitled, "Anterior Lumbar Interbody Fusion using rhBMP-2 with Tapered Interbody Cages." This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of Medtronic's PYRAMID plate and who has been paid significant sums by Medtronic through royalty agreements, consulting agreements, and education training and speaking agreements.

142. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for Infuse/BMP-2. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter, Dr. Dickman represented that "approval of BMP would provide a significant advance for patient outcome and satisfaction following spinal fusion."

143. In the October 2002 issue of JSDT touting the benefits of Infuse/BMP-2, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards require such acknowledgement. Not only did Dr. Zdeblick fail to disclose that he profited from each and every surgery which Infuse/BMP-2 was used through rights in the exclusive delivery vehicle, his LT-Cage, but no reference whatsoever to their financial ties to Medtronic was made either by Dr. Zdeblick or Dr. Dickman.

144. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its Infuse/BMP-2 product supplant autogenous bone as the gold standard in the medical community, and utilized false statements, a fraudulent enterprise and the support of Federal funds to do so.

145. As part and parcel of Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for Infuse. As the article shows, it was actually received on March 28, 2002 or after Dr. Zdeblick had accomplished installment as the editor-in-chief, and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002.

146. At the same time Dr. Zdeblick's journal was publishing the initial article on Infuse, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout Infuse potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled "Is Infuse Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials using the LT-Cage Lumbar Tapered Fusion Device."

147. This second article was published in Vol. 2 of 2003 and once again, there was no mention of Dr. Zdeblick's financial ties to Medtronic.

148. This second article would serve as the second covert advertisement for the Infuse product, and the article states that "the purpose of our analysis was to investigate the potential statistical superiority of Infuse bone graft to autograft..."

149. This second article went on to announce the July 2002 FDA approval of rhBMP-2.

150. This article included as an "acknowledgment" an expression of gratitude to the physicians "who provided patients for this study and to the clinic research group at Medtronic Sofamor Danek for their help in data collection and statistical analyses." However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.

151. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of Medtronic's fraudulent enterprise. However, unchecked by appropriate peer review, Medtronic was able to systematically accomplish their goals.

152. In its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick's 2003 as reporting that Infuse "...may become the new gold standard in spinal fusion surgery."

153. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, "Infuse Bone Graft quickly became the gold standard for certain types of lumbar fusion."

154. Medtronic's fraudulent scheme was successful and resulted in a revenue stream ranging from 700 to 900 million dollars per year.

155. It has been reported that around the same time these stories about Infuse were published, editors at the Spine Journal began receiving complaints from doctors around the country who were pointing out contradictions between papers published by doctors with financial ties to Medtronic and other data involving Infuse complications.' See *Journal Sentinel* article of John Fauber.

156. Through the use of these sham consulting, royalty and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly and potentially deliberate,

conscious, or reckless indifference in the fraudulent enterprise and fraudulent concealment. See Mississippi case.

157. Defendants had full knowledge of all these facts pertaining to Medtronics.

VI. FDA PUBLIC HEALTH NOTIFICATION

158. On July 1, 2008 the FDA issued a Public Health Notification entitled "Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion."

159. This notification was sent to health care practitioners all across the United States warning of the complications associated with BMP-2, specifically when used in the cervical spine.

160. In the notification the FDA stated they received at least 38 reports of complications during the prior four years with the use of BMP-2 in cervical spine fusions.

161. The complications were associated with swelling of the neck and throat areas, which resulted in compression of the airway and/or neurological structures in the neck.

162. Some reports describe difficulty swallowing, breathing or speaking and severe dysphagia following cervical spine fusion using BMP-2 products had also been reported.

163. The notification further stated that, "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

164. The Notification further emphasized the importance of fully informing patients of these potential risks and said that patients treated with BMP-2 in the cervical spine should know:

s. The signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area

t. That they need to seek medical attention immediately at the first sign of an airway complication

u. That they need to be especially watchful 2-14 days after the procedure when airway complications are more likely to occur

v. rhBMP-2 (contained in Infuse Bone Graft) has received pre-market approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury

165. Additionally, BMP is not approved in any manner for use in patients who are skeletally immature (<18 years of age) or pregnant.

166. Dr. Durrani and the Hospitals ignored ALL of these warnings and used BMP-2 in cervical spine surgeries, children, and those with known compromising factors such as osteoporosis, smoking, and diabetes.

167. Furthermore, the Notification stated that the FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

168. The Hospitals that allowed Dr. Durrani to use BMP-2 in their facilities failed to report any complications resulting from his use of BMP-2.

VII. SENATE FINANCE COMMITTEE REPORT

169. Medtronic's actions did not go unnoticed, and in June of 2011 the Senate Finance Committee began an investigation into the fraudulent actions of Medtronic.

170. Medtronic produced more than 5,000 documents pertaining to 13 different studies of BMP-2 for the investigation.

171. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products.

172. The investigation revealed that Medtronic employees collaborated with physician authors to edit and write segments of published studies on BMP-2/Infuse without publicly disclosing this collaboration.

173. These fraudulently-produced studies may have inaccurately represented BMP-2's risks and may have placed added weight on the side effects of alternative treatments.

174. The Senate investigation further found that Medtronic also maintained significant, previously undisclosed financial ties with physicians who authored studies about BMP-2, making $210 million in payments to physicians over a 15-year period.

175. Senator Baucus stated, "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies

distort the facts the way Medtronic has. Patients everywhere will be better served by a more open, honest system without this kind of collusion."

176. Senator Grassley stated, "The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and the studies they feature. These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

177. *Major findings of the investigation include:*

a. Medtronic was involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's role in authoring or substantially editing these articles was not disclosed in the published articles. Medical journals should ensure that any industry role in drafting articles or contributions to authors is fully disclosed.

b. Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with BMP-2/Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

d. Medtronic officials inserted language into studies that promoted BMP-2 as a better technique than an alternative by emphasizing the pain associated with the alternative.

e. Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to BMP-2 being approved. At the time, the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.

f. Medtronic documents show the company successfully attempted to adopt weaker safety rules for a clinical trial studying BMP-2 in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

VIII. YODA STUDY

178. In response to the various controversies surrounding BMP-2/Infuse, including a June 2011 article in the journal *Spine*, the Yale University Open Data Access (YODA) team reached an agreement for Medtronic to provide full individual participant data from all their trials of rhBMP-2 and allow unrestricted independent re-analysis of this data.

179. The YODA study involved research teams at two universities – the University of York and the Oregon Health and Science University.

180. The review focused exclusively on the use of rhBMP-2 in patients undergoing spinal fusion surgery for treatment of degenerative disc disease, spondylolisthesis, or any other relevant spinal condition.

181. The three main objectives of the study were: 1) to examine the potential benefits of BMP-2, 2) to examine the potential harms of BMP-2, and 3) to assess the reliability of the published evidence base.

182. Medtronic submitted data from 17 studies, including 12 randomized controlled trials (RCTs).

183. In total, the YODA study analyzed the data from 1,409 participants.

184. Though the results showed moderate success with fusions as a result of BMP-2, the study found that BMP-2 results in several different complications including: arthritis, implant-related events, retrograde ejaculation, wound complications, and neurological, urogenital, and vascular events.

185. In regard to the alleged tampering with the peer-reviewed studies by Medtronic, the YODA study found that only two out of twenty peer-reviewed journal publications reported a comprehensive list of all adverse events that occurred during the studies.

186. Furthermore, the way in which adverse event data was presented in the literature was inconsistent, and the rationale for presenting some adverse events but not others was rarely clear.

187. The study concluded that for the period up to 24 months after surgery, treatment with BMP-2 increases the probability of successful fusion (according to Medtronic definitions and reports, which the study noted "were subjective so it is not possible to confirm whether reported successful fusions truly were successful" see YODA Study, p. 35) but this does not translate to clinically meaningful benefits in pain reduction, function, or quality of life. The small benefits in these outcomes observed from six months onward

come at the expense of more pain in the immediate post-operative period and a possible increased risk of cancer.

188. Even more relevant to the case against Dr. Durrani and the Hospitals is the YODA study's conclusion that, "[i]t is very important that these findings are expressed clearly and discussed with patients so that they can make informed choices about the type of surgery they would prefer." *Id.*

189. The University of Oregon Study determined that Infuse/BMP-2 is not better than Autograft, while the University of York study determined that Infuse/BMP-2 offers only a slight and not statistically significant advantage over Autograft.

190. The YODA study concluded that Medtronic "misrepresented the effectiveness and harms through selective reporting, duplicate publication, and underreporting."

191. Adverse event categories such as heterotopic bone formation, osteolysis, and radiculitis were not included in participant databases or internal reports; therefore, the safety profile was not fully assessed.

192. The YODA study further concluded that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles on Infuse/BMP-2 authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles.

193. Medtronic paid a total of approximately $210 million to the physician authors of Medtronic-sponsored studies on Infuse from November 1996 through 2010 for consulting, royalty and other arrangements.

194. An email exchange showed that a Medtronic employee recommended against publishing a complete list of adverse events or side effects possibly associated with Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

195. Medtronic officials inserted language into studies that promoted Infuse as a better technique than an alternative procedure by overemphasizing the pain associated with the alternative procedure.

196. Medtronic's actions violated the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. See United States Senate Committee on Finance, October 2012.

197. Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components are a tapered metallic spinal fusion cage (NOT PLASTIC), a recombinant human (BMP) bone Morphogenetic Protein, and a carrier/scaffold for the BMP and resulting bone. The Infuse product is inserted into the LT-CAGE Lumbar tapered Fusion Device component to form the complete Infuse Bone Graft/LT–Cage Lumbar Tapered Fusion Device. These components must be used as a system. The Infuse Bone Graft component must not be uses without the LT-Cage Lumbar Tapered Fusion Device component.

198. BMP-2 is not supposed to be used in minors.

199. BMP-2 is not supposed to be used with smokers and diabetics because of vascular slowing.

200. BMP-2 should not be used with women in child bearing years.

201. BMP-2 is contraindicated for patients with a known hypersensitivity to rhBMP-2 and should not be used in the vicinity of a resected or extant tumor, in patients with active malignancy, or in patients undergoing treatment for a malignancy.

IX. DR. DURRANI AND BMP-2

202. Despite all of these warning signs, Dr. Durrani, with the full knowledge of the Defendants, continued to use BMP-2 in ways not approved by the FDA, or in an "off-label" manner.

203. As early as 2007, Dr. Durrani and UC Health knew there were issues with BMP-2 because insurance companies such as Anthem were refusing to pay for BMP-2.

204. Medtronic provided in writing to Dr. Durrani and CAST the approved uses for Infuse/BMP-2.

205. However, Dr. Durrani and the Defendants continued to use BMP-2 in off-label ways, including but not limited to:

a. Using BMP-2/Infuse in children, despite Medtronic specifically requiring it be used only in "skeletally mature patients;"

b. Using it outside the L2-S1 level of the spine;

c. Ignoring the requirement that BMP-2/Infuse only be used for Grade 1 spondylolisthesis or Grade 1 retrolisthesis;

d. Not requiring at least six months of non-operative treatment prior to the use of BMP-2/Infuse;

e. Using BMP-2/Infuse without the required cage;

f. Not using the "carrier scaffold" in conjunction with BMP-2/Infuse as required;

g. Using BMP-2/Infuse without proper training despite Medtronic's warning, "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience."

206. Dr. Durrani was a paid consultant for Medtronic.

207. According to Dr. Durrani's own deposition testimony in several cases, Medtronic required one of their representatives to be present in the operating room when its product BMP-2/Infuse is used.

208. Because Medtronic representatives were present in these surgeries, Medtronic knew when Dr. Durrani used BMP-2/Infuse outside the approved uses according to Medtronic's own guidelines.

209. Dr. Durrani was encouraged by Medtronic to obtain peer review and published studies from Medtronic sales representatives to support his use of BMP-2/Infuse.

210. Dr. Durrani was encouraged by Medtronic to be an advocate for his patients and describe how BMP-2/Infuse technology can benefit them.

211. When asked how he got his Medtronic grant, Dr. Durrani responded, "You apply to the Medtronic's corporate and say this is what we want to do, like everybody else in the country applies, and then they come and evaluate the thing and say, "Okay, we think it's worthy. We'll give you the grant."

212. In regard to his role as a Medtronic consultant, Dr. Durrani stated, "If there are certain products that they help us in developing, then they will come to us for a certain consultant role for a certain product development."

213. Dr. Durrani also stated, "I was involved in the development of the minimally invasive spine instrumentation."

214. Dr. Durrani gave conflicting reports on his financial relationship with Medtronic.

215. In a deposition, when asked when his relationship with Medtronic began, Dr. Durrani responded "2000-it's 2003, '04. Something in that category. I'm not sure. It's on the Medtronic website. You can go look at it."

216. Medtronic's website has no information regarding their relationship with Dr. Durrani.

217. In another deposition, Dr. Durrani stated he began his relationship with Medtronic in "2005 or '06."

218. Dr. Durrani also gave conflicting reports on how much compensation he received from Medtronic for his consultation services.

219. In one deposition, Dr. Durrani stated in response to an inquiry as to how much payment he received, "It's a standard compensation. Again, it's on the website, how much they've paid us."

220. Again, this information is not available on the Medtronic website.

221. In another deposition, when asked if he received income from Medtronic, Dr. Durrani replied, "No, I don't."

222. When questioned further if he received a fee as a consultant, he stated, "If you do a work, there is a contractual obligation that they have to pay you. As I told you in my last deposition, they did declare it on their website, so you can actually go on the website and see how much they paid."

223. In another deposition, Dr. Durrani stated that he received, "less than $10,000 in ten years" from Medtronic.

224. An email dated July 30, 2008 from Medtronic Senior Product Manager Katie Stamps to Dr. Durrani states that she "is in the process of working on the renewal of your [Dr. Durrani's] consulting agreement." As stated, this information is not available on Medtronic's website, nor is any information relating to Dr. Durrani's role as a consultant for Medtronic.

225. A CCHMC packet relating to its Orthopedics department indicated that Dr. Durrani received $60,000 in grants, contracts, or industry agreements from Medtronic Sofamor Danek in FY 2008.

226. Financial information discovered concerning Dr. Durrani's relationship with Medtronic was found in Dr. Durrani's biography on the website for the Orthopaedic & Spine Institute, which Dr. Durrani currently operates in Pakistan. The biography states that "Dr. Atiq Dr. Durrani has also received the Clinical Spine Fellowship Grant by the Department of Orthopaedic Surgery which was funded by Medtronic Sofamor Danek with a budget of $59,170 per year." See http://www.osi.com.pk/doctor/dr-atiq-Dr. Durrani-md/.

227. When a request was made to Medtronic regarding its affiliation with Dr. Durrani, the Medtronic Supplier Relations Team stated that Dr. Durrani's "name [is] not listed in our system."

228. Medtronic further responded to the Deters Law Firm's request that the firm would need a "Vendor I.D. Number," which neither Medtronic nor any other party has provided.

229. David Rattigan, was Dr. Durrani's main Medtronic representative from Bahler Medical.

230. David Rattigan and Medtronic have the same lawyer. Despite the Deters Law Firm's willingness to cooperate in scheduling the date for a deposition, they have refused until recently. Mr. Rattigan's deposition was taken June 5, 2015.

231. In summary, clients of the Deters Law Firm, with the full knowledge and intentional consent of all Defendants, became unsuspecting experiments for real world testing of Medtronic hardware and BMP-2, by and through Dr. Durrani and CAST, who had secret financial connections to Medtronic, improper motives, and submitted false claims. The government paid for many of these improper and unregulated experiments as a result of the false claims made by Dr. Durrani, with the knowledge of Medtronic, under the veil of "medically necessary" surgeries.

232. Despite repeated requests, Medtronic has refused to cooperate in providing any requested information and is actively downplaying their connections to Dr. Durrani.

X. THE DEFENDANTS AND BMP-2

233. The purpose of the background information on the following Defendants and BMP-2 concerning other hospitals is to show the egregious methods, which upon information and belief were used at all hospitals.

234. The Defendants allowed and encouraged these practices by Dr. Durrani for the sole purpose of money and greed.

235. David Rattigan was always present in Dr. Durrani's operating rooms as a representative of Medtronic.

236. David Rattigan's sole job was to deliver the BMP-2/Infuse to the Hospitals and make sure that it was inserted correctly into the patient.

237. David Rattigan's presence in the OR further supports the Defendants awareness of Dr. Durrani's fraudulent use of BMP-2/Infuse.

238. **Informed Consent for Surgical or Medical Procedure and Sedation:**

It is the responsibly of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

a. The explanation of the procedure

b. The benefits of the procedure

c. The potential problems that might occur during recuperation

d. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

e. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

f. The likelihood of achieving satisfactory results

Completion of the "Consent to Hospital and Medical Treatment" form to examine and treat is NOT sufficient as consent to perform a surgical procedure, invasive procedure, or for medical regimens of substantial risk or that are the subject of human investigation or research.

236. The Defendants had the responsibility to carry out these consent rules.

237. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

238. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

239. Dr. Durrani is a consultant for Medtronic.

240. Defendants did not inform Plaintiffs of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

241. Medtronic, provided in writing to Dr. Durrani the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

242. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

243. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

244. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

245. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

246. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

247. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

248. Dr. Durrani and Children's Hospital personnel did not disclose to Plaintiffs their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

249. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

250. Defendants did not inform Plaintiffs that Dr. Durrani used Infuse/BMP-2 in his surgeries.

251. Plaintiffs would not have allowed BMP-2 to be used by Dr. Durrani in his surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

252. Plaintiffs would not have consented to the use of BMP-2 in Plaintiff's body if informed of the risks by Dr. Durrani or any Children's Hospital personnel.

253. The written informed consent of Dr. Durrani signed by Plaintiffs lacked the disclosure of Infuse/BMP-2's use in his procedures.

254. Plaintiffs never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani or any Children's Hospital personnel.

255. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

256. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

257. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

258. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

259. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

INFUSE/BMP-2

260. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

261. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

262. Dr. Durrani is a consultant for Medtronic.

263. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

264. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

265. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

266. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

267. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4

to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

268. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

269. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

270. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

271. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

272. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

273. Plaintiff was not informed by Defendants that Dr. Durrani used Infuse/BMP-2 in her surgeries.

274. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

275. Plaintiff would not have consented to the use of BMP-2 in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

276. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in their procedure(s).

277. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

278. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

279. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

280. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

281. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

282. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

PUREGEN

283. Dr. Durrani oftentimes used Puregen when performing surgeries.

284. Puregen is a product produced by Alphatec Spine.

285. Dr. Durrani was and is a paid consultant for Alphatec Spine.

286. Dr. Durrani has an ownership stake in the Alphatec Spine.

287. Puregen has never been approved by the FDA for any human use.

288. Puregen is now removed from the market for any use.

289. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.

290. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.

291. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.

292. Plaintiff was not informed by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel that Dr. Durrani used Puregen in their surgery.

293. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA.

294. Plaintiff would not have consented to the use of Puregen in their body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

295. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Puregen's use in their procedures.

296. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

297. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

298. Defendant Dr. Durrani breached his duty by failing to exercise the requisite

degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

299. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: BATTERY

300. Dr. Durrani committed battery against Plaintiff by performing surgeries that were unnecessary, contraindicated for Plaintiff's medical condition, and for which he did not properly obtain informed consent, inter alia, by using BMP-2, PureGen and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.

301. Plaintiff would not have agreed to the surgeries if she knew the surgeries were unnecessary, not approved by the FDA, and not indicated.

302. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: LACK OF INFORMED CONSENT

303. The informed consent forms from Dr. Durrani and CAST which they required Plaintiff to sign failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani and CAST each required an informed consent release.

304. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before Plaintiff's surgeries.

305. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with her surgeries and procedures.

306. Had Plaintiff been appropriately informed of the need or lack of need for surgeries and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgeries or procedures.

307. As a direct and proximate result of the lack of informed consent, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

308. Dr. Durrani's conduct as described above was intentional and reckless.

309. It is outrageous and offends against the generally accepted standards of morality.

310. It was the proximate and actual cause of Plaintiff's psychological injuries, emotional injuries, mental anguish, suffering, and distress.

311. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

312. Dr. Durrani made material, false representations to Plaintiff and their insurance company related to Plaintiff's treatment including: stating the surgeries were necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgeries would be simple or were "no big deal", that Plaintiff would be walking normally within days after each surgeries, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the

surgeries were successful, and that Plaintiff was medically stable and ready to be discharged.

313. Dr. Durrani also concealed the potential use of Infuse/BMP-2 and/or Puregen in Plaintiff's surgeries, as well as other information, when he had a duty to disclose to Plaintiff his planned use of the same.

314. These misrepresentations and/or concealments were material to Plaintiff because they directly induced Plaintiff to undergo her surgeries.

315. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

316. Dr. Durrani made the misrepresentations both before, during and after each surgery with the intent of misleading Plaintiff and her insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgeries, and to induce Plaintiff to undergo the surgeries without regard to medical necessity and only for the purpose of receiving payment.

317. The misrepresentations and/or concealments were made during Plaintiff's office visits at Dr. Durrani's CAST offices.

318. Plaintiff was justified in her reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

319. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgeries which were paid for in whole or in part by her insurance company, and suffered all damages as requested in the Prayer for Relief.

COUNT VI: SPOLIATION OF EVIDENCE

320. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

321. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

322. Dr. Durrani's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

CAST COUNTS:

COUNT I: VICARIOUS LIABILITY

323. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of CAST.

324. Dr. Durrani is in fact, the owner of CAST.

325. Defendant Dr. Durrani was performing within the scope of his employment with CAST during the care and treatment of Plaintiff.

326. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

327. Defendant CAST is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

328. As a direct and proximate result of Defendant CAST's acts and omissions, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: NEGLIGENT HIRING, RETENTION, AND SUPERVISION

329. CAST provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

330. CAST and Dr. Durrani participated in experiments using BMP-2 and/or Puregen bone graft on patients, including Plaintiff, without obtaining proper informed consent thereby causing harm to Plaintiff.

331. CAST breached its duty to Plaintiff, inter alia, by not supervising or controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiff at CAST.

332. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

333. Such disregard for and violations of federal law represents strong evidence that CAST negligently hired, retained, and supervised Dr. Durrani.

334. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: SPOLIATION OF EVIDENCE

335. CAST, through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

336. CAST, through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

337. CAST's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT III: FRAUD

338. Upon information and belief, Plaintiff believes the bills requested by Plaintiff will indicate that CAST falsely represented that Plaintiff's surgery was appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

339. CAST sent out billing to Plaintiff's insurance company after the surgeries at WCH/UC Health.

340. The exact dates these medical bills were sent out are reflected in those medical bills.

341. These bills constituted affirmative representations by CAST that the charges related to Plaintiff's surgeries were medically appropriate and properly documented.

342. The bills were sent with the knowledge of CAST that in fact Plaintiff's surgeries were not appropriately billed and documented and that the services rendered at WCH/UC Health associated with Dr. Durrani were not appropriate.

343. The bills sent by CAST to Plaintiff falsely represented that Plaintiff's surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

344. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing

Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for CAST's services in association with Dr. Durrani's surgery.

345. As a direct and proximate result of this reliance on the billing of CAST, Plaintiff incurred medical bills that she otherwise would not have incurred.

346. CAST also either concealed from Plaintiff that they knew about Dr. Durrani, including that Infuse/BMP-2 and/or Puregen would be used in Plaintiff's surgeries, or misrepresented to Plaintiff the nature of the surgeries, and the particular risks that were involved therein.

347. CAST's concealments and misrepresentations regarding Infuse/BMP-2 and/or Puregen and the nature and risks of Plaintiff's surgeries were material facts.

348. Because of its superior position and professional role as a medical service provider, CAST had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

349. CAST intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgeries, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at Journey Lite.

350. Plaintiff was unaware that BMP-2 and/or Puregen would be used in Plaintiff's surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 and/or Puregen's use in Plaintiff's spine.

351. Had Plaintiff known before Plaintiff's surgeries that Infuse/BMP-2 and/or Puregen would be used in Plaintiff's spine and informed of the specific, harmful risks

flowing therefrom, Plaintiff would not have undergone the surgery with Dr. Durrani at WCH/UC Health.

352. Upon information and belief, Plaintiff believes the bills requested by Plaintiff will indicate that CAST falsely represented that Plaintiff's surgery was appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.

353. Plaintiffs are still awaiting itemized billing from CAST reflecting the exact totals charged for the use of Infuse BMP-2 and/or Puregen.

354. As a direct and proximate result of the fraud against plaintiff by CAST, Plaintiff sustained all damages requested in the prayer for relief.

WEST CHESTER HOSPITAL/UC HEALTH COUNTS:

COUNT I: NEGLIGENCE

355. West Chester Hospital/UC Health owed their patient, Plaintiff, through its agents and employees the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

356. West Chester Hospital/UC Health acting through its agents and employees breached their duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgeries, improper performance of the surgeries, improper assistance during Plaintiff's surgeries and improper follow up care addressing a patient's concerns.

357. The agents and employees who deviated from the standard of care include nurses,

physician assistants, residents and other hospital personnel who participated in Plaintiff's surgeries.

358. The management, employees, nurses, technicians, agents and all staff during the scope of their employment and/or agency of West Chester Hospital/UC Health's knowledge and approval, either knew or should have known the surgeries were not medically necessary based upon Dr. Durrani's known practices; the pre-op radiology; the pre-op evaluation and assessment; and the violation of their responsibility under the bylaws, rules, regulations and policies of West Chester Hospital/UC Health.

359. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care by the agents and employees of West Chester Hospital/UC Health, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: NEGLIGENT CREDENTIALING, SUPERVISION, AND RETENTION

360. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiff constitute medical negligence, lack of informed consent, battery, and fraud.

361. West Chester Hospital/UC Health negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules by:

a. Allowing Dr. Durrani to repeatedly violate the West Chester Hospital/UC Health bylaws with it's full knowledge of the same;

b. Failing to adequately review, look into, and otherwise investigate Dr. Durrani's educational background, work history and peer reviews when he applied for and reapplied for privileges at West Chester Hospital;

c. Ignoring complaints about Dr. Durrani's treatment of patients reported to it by West Chester Hospital staff, doctors, Dr. Durrani's patients and by others;

d. Ignoring information they knew or should have known pertaining to Dr. Durrani's previous privileged time at other Cincinnati area hospitals, including Children's Hospital, University Hospital, Deaconess Hospital, Good Samaritan Hospital and Christ Hospital.

362. The Safe Medical Device Act required entities such as West Chester Hospital/UC Health to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

363. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: FRAUD

364. West Chester Hospital/UC Health sent out billing to Plaintiff at her home following her surgeries at West Chester Hospital.

365. The exact dates these medical bills were sent out are reflected in those medical bills.

366. These bills constituted affirmative representations by West Chester Hospital/UC Health that the charges related to Plaintiff's surgeries were medically appropriate and properly documented.

367. The bills were sent with the knowledge of West Chester Hospital/UC Health that in fact Plaintiff's surgeries were not appropriately billed and documented and that the service rendered at West Chester Hospital/UC Health associated with Dr. Durrani was not appropriate.

368. The bills sent by West Chester Hospital/UC Health to Plaintiff's falsely represented that Plaintiff's surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

369. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for West Chester Hospital/UC Health's services in association with Dr. Durrani's surgeries.

370. West Chester Hospital/UC Health concealed information they knew about Dr. Durrani, including BMP-2/Puregen, from Plaintiff which if not concealed Plaintiff would not have allowed Dr. Durrani to perform surgeries.

371. As a direct and proximate result of the fraud upon Plaintiffs by West Chester Hospital/UC Health, Plaintiff sustained all damages requested in the Prayer for Relief.

372. West Chester Hospital/UC Health also either concealed from Plaintiff facts they knew about Dr. Durrani, including that Infuse/BMP-2 or Puregen would be used in

Plaintiff's surgeries, or misrepresented to Plaintiff the nature of the surgeries, and the particular risks that were involved therein.

373. West Chester Hospital/UC Health's concealments and misrepresentations regarding Infuse/BMP-2 or Puregen and the nature and risks of Plaintiff's surgeries were material facts.

374. Upon information and belief, WCH/ UC Health billed Plaintiff for "OR ALLOGRAFTS" in the amount of $10,472.44 and billed Plaintiff for "OR IMPLANT MISC" in the amount of $3270.75 for Plaintiff's September 30, 2009 surgery. Upon information and belief, Plaintiff believes these products are Infuse/BMP-2 and/ or Puregen and that West Chester Hospital/ UC Health concealed the description of the products.

375. Because of its superior position and professional role as a medical service provider, West Chester Hospital/UC Health had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

376. West Chester Hospital/UC Health intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgeries, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at West Chester Hospital/UC Health.

377. Plaintiff was unaware that Infuse/BMP-2 or Puregen would be used in Plaintiff's surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiff's spine.

378. Had Plaintiff known before Plaintiff's surgeries that Infuse/BMP-2 or Puregen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing

therefrom, Plaintiff would not have undergone the surgeries with Dr. Durrani at West Chester Hospital/UC Health.

379. Plaintiff is still awaiting the requested itemized billing for her January 18, 2010 surgery.

380. As a direct and proximate result of the fraud upon Plaintiff by West Chester Hospital/UC Health, Plaintiff sustained all damages requested in the prayer for relief.

COUNT IV: SPOLIATION OF EVIDENCE

381. West Chester Hospital/UC Health through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

382. West Chester Hospital/UC Health through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

383. West Chester Hospital/UC Health's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT V: OHIO CONSUMER SALES PROTECTION ACT

384. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

385. West Chester Hospital/UC Health's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

386. West Chester Hospital/UC Health omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

387. West Chester Hospital/UC Health's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

388. West Chester Hospital/UC Health was fully aware of its actions.

389. West Chester Hospital/UC Health was fully aware that Plaintiffs were induced by and relied upon West Chester Hospital/UC Health's representations at the time West Chester Hospital/UC Health was engaged by Plaintiffs.

390. Had Plaintiffs been aware that West Chester Hospital/UC Health's representations as set forth above were untrue, Plaintiffs would not have used the services of the Defendants.

391. West Chester Hospital/UC Health, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

392. West Chester Hospital/UC Health's actions were not the result of any bona fide errors.

393. As a result of West Chester Hospital/UC Health's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring West Chester Hospital/UC Health restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

COUNT VI: PRODUCTS LIABILITY

394. At all times Infuse/BMP-2 and Puregen are and were products as defined in R.C. § 2307.71(A)(12) and applicable law.

395. West Chester Hospital/UC Health (aka supplier) supplied either Medtronic's (aka manufacturer) Infuse/BMP-2 or Alphatec Spine's (aka manufacturer) Puregen for surgery performed by Dr. Durrani on Plaintiff.

396. West Chester Hospital/UC Health, as a supplier, failed to maintain either Infuse/BMP-2 or Puregen properly.

397. West Chester Hospital/UC Health did not adequately supply all components required to use either Infuse/BMP-2 or Puregen properly.

398. West Chester Hospital/UC Health knew or should have known the FDA requirements and Medtronic's requirements for using either Infuse/BMP-2 or Puregen.

399. West Chester Hospital/UC Health stored either Infuse/BMP-2 or Puregen at its facility.

400. West Chester Hospital/UC Health ordered either Infuse/BMP-2 or Puregen for surgery performed by Durrani.

401. West Chester Hospital/UC Health did not adequately warn Plaintiff that either Infuse/BMP-2 or Puregen would be used without all FDA and manufacturer required components.

402. West Chester Hospital/UC Health did not gain informed consent from Plaintiff for the use of either Infuse/BMP-2 or Puregen, let alone warn of the supplying of the product without FDA and manufacturer requirements.

403. West Chester Hospital/UC Health failed to supply either Infuse/BMP-2 or Puregen (aka product) in the manner in which it was represented.

404. West Chester Hospital/UC Health failed to provide any warning or instruction in regard to either Infuse/BMP-2 or Puregen, and failed to make sure any other party gave such warning or instruction.

405. West Chester Hospital/UC Health intentionally billed Infuse/BMP-2 and/or Puregen as "Miscellaneous" to prevent discovery of the use of Infuse/BMP-2 and/or Puregen by Plaintiffs.

406. Plaintiff suffered physical, financial, and emotional harm due to West Chester Hospital/UC Health's violation of the Ohio Products Liability act. Plaintiff's injuries were a foreseeable risk

407. Plaintiff did not alter, modify or change the product, nor did Plaintiff know that the product was being implanted without all required components.

408. West Chester Hospital/UC Health knew or should have known that the product was extremely dangerous and should have exercised care to provide a warning that the

product was being used and that the product was being used outside FDA and manufacturer requirements. The harm caused to Plaintiff by not providing an adequate warning was foreseeable,

409. West Chester Hospital/UC Health knew that the product did not conform to the representation of the intended use by the manufacturer yet permitted the product to be implanted into Plaintiff.

410. West Chester Hospital/UC Health, as a supplier, acted in an unconscionable manner in failing to supply the product without all FDA and manufacturer required components.

411. West Chester Hospital/UC Health, as a supplier, acted in an unconscionable manner in failing to warn Plaintiff that the product was being supplied without all FDA and manufacturer required components.

412. West Chester Hospital/UC Health's actions demonstrate they took advantage of the Plaintiffs inability, due to ignorance of the product, to understand the product being implanted without FDA and manufacturer required components.

413. West Chester Hospital/UC Health substantially benefited financially by the use of the product as the product allowed for West Chester Hospital/UC Health to charge more for the surgery.

414. Plaintiff suffered economic loss as defined in R.C. § 2303.71(A)(2) and applicable law.

415. Plaintiff suffered mental and physical harm due to West Chester Hospital/UC Health's acts and omissions.

416. Plaintiff suffered emotional distress due to acts and omissions of West Chester Hospital/UC Health and is entitled to recovery as defined in R.C. § 2307.71(A)(7) and applicable law.

417. West Chester Hospital/UC Health violated the Ohio Products Liability Act R.C. § 2307.71-2307.80

418. West Chester Hospital/UC Health violated R.C. § 2307.71(A)(6)

419. West Chester Hospital/UC Health violated The Ohio Consumer Sales Practices Act R.C. § 1345.02-.03.

420. West Chester Hospital/UC Health provided inadequate warnings are defined in R.C, § 2307.76(A) and applicable law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request and seek justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;
2. Future medical bills;
3. Lost income and benefits;
4. Lost future income and benefits;
5. Loss of ability to earn income;
6. Past pain and suffering;
7. Future pain and suffering;
8. Plaintiff seeks a finding that their injuries are catastrophic under Ohio Rev. Code §2315.18;
9. All incidental costs and expenses incurred as a result of their injuries;
10. The damages to their credit as a result of their injuries;

11. Punitive damages;

12. Costs;

13. Attorneys' fees;

14. Interest;

15. All property loss;

16. All other relief to which they are entitled including O.R.C. 1345.01

Based upon 1-17 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of $25,000.

Respectfully Submitted,

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Lindsay Boese (0091307)
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JURY DEMAND

Plaintiffs make a demand for a jury under all claims.

Matthew Hammer (0092483)
Lindsay Boese (0091307)

UC Health

ITEMIZED BILL

5/23/2014

P.O. Box 740117
Cincinnati, OH 45274-0117

Patient Name: Last	First	Account Number	Admit Date	Discharge Date	Age	Gender
GRIMM	JENNY	2181153710000	09/30/2009	10/01/2009	49	F

WEST CHESTER MEDICAL CENTER

GRIMM JENNY L
134 GARVEY AVENUE
ELSMERE KY 41018

Payment Using Credit Card

☐ M/C ☐ Visa ☐ Discover ☐ AMEX

Card Number

Signature | Exp Date

Show Payment Amount Here $

Return this portion with your payment

Service Date	Key Hsp Code	CPT/HCPS	Activity	Transaction Amount
09/30/2009	00272		OR MED SURG SUPPLY	$1263.60
09/30/2009	00278		OR IMPLANT MISC	$3270.75
09/30/2009	00278		OR SPINAL CAGE	$8137.58
09/30/2009	00278		OR ALLOGRAFTS	$10472.44
09/30/2009	00278		OR SPINAL SCREW	$3375.38
09/30/2009	00300	36415	PHLEBOTOMY	$17.00
09/30/2009	00300	86901	RH	$25.00
09/30/2009	00300	86850	ANTIBODY SCREEN: EACH INCUBATION	$91.00
09/30/2009	00300	86900	ABO TYPE	$41.00
09/30/2009	00320	72020	DIAG C SPINE SINGLE VIEW	$234.00
09/30/2009	00320	76000	DIAG FLOURO UP TO 1 HOUR	$473.00
09/30/2009	00360		OR - CONTR SVC - 1ST HALF HOUR	$7775.00
09/30/2009	00360		OR - CONTR SVC - EACH ADDL MINUTE	$10080.00
09/30/2009	00370		AN - COMPLEX - 1ST HALF HOUR	$543.00
09/30/2009	00370		AN - COMPLEX - EACH ADDITIONAL MINUTE	$2692.00
09/30/2009	00412	94640	RC HHN TREATMENT	$70.00
09/30/2009	00710		SDSC-PREOP LEVEL I-OTPT AMBULATORY 1/2HR	$0.00
09/30/2009	00710		PACU - POST OP TYPE 4:UP TO 1ST HOUR	$865.00
09/30/2009	00710		PACU - POST OP TYPE 4: EA ADDL 1/2 HOUR	$678.00
09/30/2009	00980		IMPLANTABLE DEVICE INDICATOR	$0.00
10/01/2009	00250		ASPIRIN 81MG TAB CHEW	$1.55
10/01/2009	00250		CALCIUM CARBONATE 1.25G TABLET	$3.60
10/01/2009	00250		MULTIVITAMINS:THERAPEUTIC TAB PO	$3.65
10/01/2009	00250		ASCORBIC ACID 500MG TAB	$3.65
10/01/2009	00250		OXYCODONE HCL/APAP 5-325MG TAB PO	$72.75
10/01/2009	00251		METHOCARBAMOL 100MG/ML VIAL INJ	$195.40
10/01/2009	00251		METOCLOPRAMIDE HCL 10MG INJ	$43.30
10/01/2009	00251		PNEUMOCOCCAL VACCINE VIAL INJ	$122.70
10/01/2009	00251		Dexamethasone 4mg/ml Injection 1ml	$43.90

Affidavit of Merit

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned state as follows:

1. I have reviewed all relevant medical records reasonably available about Jenny Grimm concerning the allegations of medical negligence.

2. I am familiar with the applicable standard of care.

3. Based upon my review of this record, my education, my training, and experience, it is my belief, to a reasonable degree of medical certainty that the care provided by the Defendants Dr. Durrani, CAST, UC/West Chester Hospital was negligent, and this negligence caused injury to Jenny Grimm, *inter alia,* negligent and unnecessary surgery, negligent surgical techniques, failure to maintain accurate and complete surgical records, unnecessary pain management procedures based on fraudulent, inaccurate, and/or exaggeration of medical records, failure to maintain complete and accurate surgical consent forms, negligent selection and implantation of hardware, failure to obtain proper informed consent for use, use of unapproved allograft/hardware combination, implantation of Infuse in multiple levels of the spine, failure to provide adequate/complete pre and post-operative patient surgical education and monitoring, failure to supervise Dr. Durrani, negligent pre- surgical diagnosis, improper documentation, health care fraud, battery, negligent treatment, practicing outside the scope of training, education, experience, and Board certifications, and medical negligence.

4. Jenny Grimm is a now 57 year old married Caucasian female, currently on total disability SSI. She has a positive two pack per day smoking history, spanning over forty years. She denies alcohol or illicit drug use. Her medical history includes Diabetes Mellitus Type II, hypertension , hyperlipidemia, endometriosis, anemia, arthritis, cancer/tumor, depression/anxiety, GERD, emphysema/COPD, Irritable bowel syndrome. Her past surgical history prior to seeing Dr. Durrani includes tonsillectomy '80, disc repair '88, plates implanted '92, battery removed bone stimulator '93, appendectomy '97, total hysterectomy '97. She has medication allergies to Levaquin, Codeine.

5. Jenny Grimm began with onset of lower back pain in her 20's, and was diagnosed with degenerative disk disease. She had a fall at work, at which point she had some xrays and it was diagnosed. She had disc surgery in 1988, and a fusion by Dr. John Schmitz in 1992. She was able to return to work for another seven years after the second surgery in 1992. She had recurrence of pain in approximately 2000, and sought out pain management services with Dr. John Kelly of Neuroscience Associates of Northern Kentucky, where she is still an active patient.

6. On 06/25/09, Jenny Grimm completed an L-Spine MRI at St. Elizabeth Medical center, ordered by Dr. John Kelly. The MRI revealed a fusion performed at L4-5 and L5-S1 levels with pedicle screws. There is significant metallic ferromagnetic artifact at these levels. The disc spaces at L3-4, L4-5, and L5-S1 are difficult to evaluate and clinical correlation necessary. CT myelography may be necessary as well to further evaluate these discs given the metal artifact. However, limited evaluations of these discs do not reveal significant canal stenosis or disc protrusions at these levels. Possible anterior subluxation*(A vertebra in the spine that is out of alignment with the rest of the vertebrae)* of L3-4, but could be artifactual related to the metal artifact. Shallow protrusions suspected at L5-S1, L2-3, and to lesser extent, L1-2 and T12-L1. No high canal stenosis or obvious foraminal narrowing seen from limited study.

7. On 06/25/09, Jenny Grimm completed a C-Spine MRI, ordered by Dr. John Kelly, at St. Elizabeth Medical Center. The MRI revealed C2-3 shows no disc herniation or compression, C3-4 shows mild diffuse disc bulging and somewhat short pedicles which producing mild cord compression, C4-5 shows no disc herniation or compression, C5-6 shows mild diffuse disc bulging with mild ventral flattening of the cord, and mild to moderate narrowing of left C6 neural foramen. C6-7, C7-T1, T1-T2 show no disc herniation or neural compression.

8. On 07/31/09, Jenny Grimm completed a C-Spine xrays, ordered by Dr. Durrani, at St. Elizabeth Medical Center. The xrays revealed loss of the normal lordosis of the cervical spine but no evidence of frank misalignment. There are degenerative changes globally. Endplate sclerosis and hypertrophy of the posterior elements are noted. Foraminal narrowing at multiple levels. Radiographically, the disease appears to be most prominent at C3-4 and C4-5 on the right, and C3-4 on the left. Also apparent partial congenital fusion of C2 and C3.

9. On 07/31/09, Jenny Grimm completed an L-Spine xrays, ordered by Dr. Durrani, at St. Elizabeth Medical Center. The xrays revealed severe degenerative disk disease L5-S1. Moderate degenerative disk disease L3-4 with anterolisthesis of L3 on L4 of 1mm.

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10. **Dr. Durrani's prior knowledge of possible complication and failure to practice due diligence, CAST's prior knowledge of possible complication and failure to practice due diligence, Order of unnecessary surgery, Negligent pre- surgical diagnosis, Inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure to maintain a complete and accurate medical record, Failure to properly educate patient regarding diagnoses, Fraudulent, negligent and reckless preoperative work up, Patient financial loss due to physician ordering of unnecessary, expensive tests and procedures based on inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure by Dr. Durrani at CAST to disclose pertinent health information to client, Failure to adhere to professional conduct policy of a physician -** On 08/06/09, Jenny Grimm attended an initial consultation with Dr. Durrani at CAST, after being referred by Dr. Stephen Brooks, her primary care physician. Dr. Durrani dictates, "She is here for three different reasons. One is a neck pain and mid thoracic pain, second is lower back pain, and third is an inability to stand up straight i.e. kyphotic deformity. On exam today, she is very tender in the neck. She is unable to keep her neck straight. Her neck goes in a flexed position. She has a significant kyphotic deformity in the middle of the thoracic spine. The x-rays show she has a very significant kyphotic deformity and she is in positive sagittal balance, which is very significant. The x-rays also show she has a very significant cervical disc collapse at C5-6, C6-7, C7-T1. The x-rays also shows that she has a grade 1 coming to 2 degenerative spondylolisthesis at L3-4, which is above the level of her previous fusion from L4-S1. The MRI confirms those findings and show the spinal stenosis in that area. At this point, I would recommend a three stage strategy. One is to do an ACDF stage one at C5-6, C6-7, and C7-T1. Second, do a DLIF in a minimally invasive fashion at L3-4 with facet screws. Third would be a few months down the road, and would be to do a spine osteotomy and a posterior spinal fusion for her kyphotic deformity."

11. **Negligent pre- surgical diagnosis, Inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure to maintain a complete and accurate medical record, Failure to properly educate patient regarding diagnoses, Fraudulent, negligent and reckless preoperative work up, Failure to adhere to professional conduct policy of a physician, -** The cervical spine xrays taken on 07/31/09 stated there was loss of the normal lordosis of the cervical spine, but no evidence of frank malalignment. Dr. Durrani exaggerated her cervical spine condition, as he was known to do often with patients to accelerate need for surgery. There are several factors that are known to cause variations in the healthy cervical lordosis. In many cases, it is an inherited

condition. It can also be caused by injury and/or trauma, stress and strain to the neck. In most instances, cervical lordosis is caused by neglecting to maintain good posture. Osteoporosis, which is the thinning of bone tissue and loss of bone density over time (often found in the neck region), is also a cause of cervical lordosis. Obesity has been known to cause cervical lordosis as well. Obesity can affect the body's balance and center by offering a weight and strain to the body that is unnatural so the body is ill-equipped to support and maintain proper posture.

12. **Dr. Durrani's prior knowledge of possible complication and failure to practice due diligence, UC/West Chester Hospital's prior knowledge of possible complication and failure to practice due diligence, Unnecessary surgery, Negligent pre- surgical diagnosis, Inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure to maintain a complete and accurate medical record, Failure to properly educate patient regarding diagnoses, Fraudulent, negligent and reckless preoperative work up, Patient financial loss due to physician ordering of unnecessary, expensive tests and procedures based on inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure by Dr. Durrani to disclose pertinent health information to client, Failure to adhere to professional conduct policy of a physician -** Aside from the fact that Dr. Durrani's interpretations of the radiology results are vastly different than the radiologist, Mrs. Grimm was not a viable surgery candidate. Going under general anaesthesia is a risk in itself, secondary to her compromised respiratory status of emphysema/COPD, cardiac system, and a forty plus years of two packs per day smoking. Her diabetes and hypertension diagnoses compromise healing and blood flow and makes her more susceptible to infections, coupled with the fact that even with taking two glucose regulating medications; her blood sugars remained in the 200+ range. Her coronary artery disease factors of hypertension and hyperlipidemia also increase the chance of complications during and after surgery. At the time of initial consultation, client was 5'7" and 225 pounds. The morbid obesity alone would make her a greater anesthesia risk, as well as complicate physical therapy with inability to balance body mass and history of deep vein thrombosis. Excess weight decreases success rates of fusions because of extra stress placed upon a fusion. This was not addressed by Dr. Durrani. A referral to a nutritionist for an aggressive weight loss program to relieve stress on back and lower extremities, as well as a daily home exercise plan for the back. Her prior medical history includes Type 2 diabetes, hypertension, hyperlipidemia, endometriosis, anemia, arthritis, cancer/tumor, Gastro-esophageal Reflux disease, emphysema/chronic obstructive pulmonary disease, irritable bowel syndrome. After acknowledging the multiple co-morbidities, Dr. Durrani still chose to move forward with the unnecessary surgery.

13. **Failure by UC/West Chester Hospital to orientate Dr. Durrani to hospital policy/procedure, Failure by Dr. Durrani at UC/West Chester Hospital to adhere to UC/West Chester Hospital's policy/procedures, Failure by UC/West Chester Hospital to audit and monitor Dr. Durrani's compliance with hospital policy/procedure, Failure to maintain a complete and accurate medical records, Failure to maintain complete and accurate surgical records, Failure to adhere to professional conduct policy of a physician, -** Dr. Durrani's documentation of his office, hospital, and surgical medical records are very poor. His notes are incomplete, inaccurate, and incorrect at multiple places with contradictory statements in multiple areas. It is virtually impossible to follow his notes as references for a timeline of care because of these inconsistencies. For example, Dr. Durrani fails to include a surgery date on Jenny Grimm's operating room report on 01/18/10.

14. **Negligent pre- surgical diagnosis, Inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure by Dr. Durrani at CAST to maintain accurate and/or complete medical records, Failure to adhere to professional conduct policy of a physician, -** Dr. Durrani's interpretation of Jenny Grimm's C-Spine MRI radiology (06/25/09) is in direct opposition with the radiologist.

Dr. Durrani listed "Cervical disc herniation at C5-6 and C6-7" as Pre-Operative diagnoses in his Operative Report. According to the 06/25/09 MRI, C5-6 shows mild bulging, NOT herniation. C6-7 shows NO disc herniation or compression of neural compression. Dr. Durrani also listed "Cervical spinal stenosis C5-6, C6-7" as Pre-Operative diagnoses in his Operative Report. According to the 6/25/09 MRI, "At the C6-7 level, NO disc herniation or compression of neural structures is seen."

15. **Prior knowledge of possible complication and not practicing due diligence, Unnecessary surgery, Negligent pre- surgical diagnosis, Inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure to maintain a complete and accurate medical record, Failure to properly educate patient regarding diagnoses, Fraudulent, negligent and reckless preoperative work up, Patient financial loss due to physician ordering of unnecessary, expensive tests and procedures based on inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure by Dr. Durrani to disclose pertinent health information with client, Failure to adhere to professional conduct policy of a physician,** -The only documented treatment for pain control was narcotic pain medication at that point. Dr. Durrani should have thoroughly reviewed Mrs. Grimm's medical records and any conservative approaches that had tried and failed, as well as thoroughly educate the patient regarding reasonable outcomes, importance of physical therapy compliance, and narcotic medication education and safety. Commonwealth Orthopedics documented that the last time chiropractic care was utilized was at least ten years ago, and also that client is uncooperative with physical therapy attempts due to pain. Dr. Durrani did not document any conservative treatment options, only surgical intervention. Dr. Durrani did not verify the length of time, validity, compliancy, or results of any of these non-surgical interventions performed prior to Dr. Durrani when evaluating Jenny Grimm.

16. **Failure by UC/West Chester Hospital to orientate Dr. Durrani to hospital policy/procedure, Unnecessary said patient health and safety risk by Dr. Durrani, Unnecessary said patient health and safety risk by UC/West Chester Hospital, Prior knowledge of possible complication and not practicing due diligence Failure by Dr. Durrani at UC /West Chester Hospital to disclose, Health care fraud, Battery, Negligent treatment, Practicing outside the scope of training, education, experience, and Board certifications, Medical negligence, Patient financial loss due to physician ordering of unnecessary, expensive tests and procedures based on inaccurate, fraudulent, and/or exaggeration of diagnoses, Negligent and unnecessary surgery, Failure by Dr. Durrani at UC /West Chester Hospital to inform patient of additional/changed procedure and reason, Grossly negligent surgical techniques, Failure to supervise, Failure by Dr. Durrani at UC /West Chester Hospital to obtain consent, Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information with client, Failure to adhere to professional conduct policy of a physician** -On 09/30/09, at UC/West Chester Hospital, Mrs. Grimm completed surgery performed by Dr. Durrani. UC/West Chester Health signed hospital consent form lists the following procedure to be completed, "C5-6, C6-7, C7-T1 Anterior Cervical Discectomy". Dr. Durrani lists procedures performed as "Anterior cervical diskectomy C5-C6, C6-C7, Anterior cervical fusion C5-6, C6-7, Placement of anterior cervical cage (DePuy) C5-6, C6-7, Anterior cervical instrumentation C5, C6, and C7 (DePuy)". Dr. Durrani dictated his OR report on 09/30/09.

17. **Failure by Dr. Durrani at UC /West Chester Hospital to perform accurate and complete postoperative teaching, Failure by Dr. Durrani at UC /West Chester Hospital to properly educate patient regarding diagnoses, Failure by Dr. Durrani and UC/West Chester Health to maintain accurate and/or complete surgical records, Failure by Dr. Durrani to adhere to signed informed consent, Failure by Dr. Durrani and UC/West Chester Health to disclose pertinent health information, Failure to adhere to professional conduct policy of a**

physician, -In the signed West Chester surgical consent form, Dr. Durrani has listed "Thoracic level One" to be surgically repaired, yet his OR report does not reflect this occurrence. The implant log from the surgery states that implants were transplanted into level T1. Dr. Durrani does not state why the T1 was not repaired, and did not share with Jenny Grimm or her family the reasons for this. Dr. Durrani and UC/West Chester Health failed to communicate important medical and surgical information to Jenny Grimm and family.

18. **Failure by UC/West Chester Hospital to orientate Dr. Durrani to hospital policy/procedure, Prior knowledge of possible complication and not practicing due diligence by Dr. Durrani at UC /West Chester Hospital, Unnecessary said patient health and safety risk by Dr. Durrani, Unnecessary said patient health and safety risk by UC/West Chester Hospital, Failure to disclose by Dr. Durrani at UC /West Chester Hospital , Health care fraud by Dr. Durrani at UC /West Chester Hospital , Battery by Dr. Durrani at UC Hospital/West Chester Hospital , Negligent treatment by Dr. Durrani at UC /West Chester Hospital, Dr. Durrani at UC /West Chester Hospital practicing outside the scope of training, education, experience, and Board certifications, Medical negligence by Dr. Durrani at UC /West Chester Hospital, Patient financial loss due to physician ordering of unnecessary, expensive tests and procedures based on inaccurate, fraudulent, and/or exaggeration of diagnoses, Negligent and unnecessary surgery by Dr. Durrani at UC/West Chester Hospital , Failure by Dr. Durrani at UC/West Chester Hospital to inform patient of additional/changed procedure and reason, Grossly negligent surgical techniques by Dr. Durrani at UC/West Chester Hospital, failure to supervise, Failure by Dr. Durrani at UC/West Chester Hospital to obtain consent, Failure by Dr. Durrani to disclose pertinent health information with client, Failure to adhere to professional conduct policy of a physician** -The Intra-Operative log indicates that Dr. Durrani used rhBMP-2 during this surgery(09/30/09). According to the PMA submitted by Medtronic to the FDA, Infuse was intended for a single level anterior lumbar interbody fusion single performed with all three components in a specific spinal region. The three components that the Infuse device consists of are 1.) A metallic spinal fusion cage (the LT-Cage), 2.) The bone graft substitute, which consists of liquid rhBMP-2, and 3.) A spongy carrier or scaffold for the protein that resides in the fusion cage. With the exception of two non-spinal uses not relevant here, the FDA has not approved any other use of Infuse, including the posterior approach used on Mrs. Grimm by Dr. Durrani. He failed to use the FDA approved cage or spongy carrier, implemented BMP in multiple levels, introduced BMP into the non FDA approved cervical area. The off label use of BMP without the expressed or written consent and/or knowledge of Mrs. Grimm is a violation of standards of care, as well as a violation of the manner in which BMP could be used, in accordance with the FDA.

19. **Failure by UC/West Chester Hospital to orientate Dr. Durrani to hospital policy/procedure, Failure by UC/West Chester Hospital to properly supervise Dr. Durrani, Non-consensual use of rhBMP-2 (Recombinant Human Bone Morphogenetic Protein, the active ingredient found in Infuse, which is a bioengineered liquid bone protein that stimulates bone growth)by Dr. Durrani at UC /West Chester Hospital, Failure by Dr. Durrani at UC/West Chester Hospital to inform patient of additional/changed procedure and reason, Failure by Dr. Durrani at CAST to inform patient of additional/changed procedure and reason Failure by UC/West Chester Hospital to disclose additional/changed procedure and reason to patient, Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information with client, Failure by Dr. Durrani at CAST to disclose pertinent health information with client, Failure to adhere to professional conduct policy of a physician,** - Infuse has been linked to nerve root irritation problems, as well as nerve root dysfunction. Another reason that this patient may have developed her neurologic problem following the

surgery. UC/West Chester Hospital has an obligation to monitor their surgeons and prevent this misuse of a product.

20. **Failure by UC/West Chester Hospital to orientate Dr. Durrani to hospital policy/procedure, Failure by UC/West Chester Hospital to properly supervise Dr. Durrani, Non-consensual use of rhBMP-2 (Recombinant Human Bone Morphogenetic Protein, the active ingredient found in Infuse, which is a bioengineered liquid bone protein that stimulates bone growth)by Dr. Durrani at UC /West Chester Hospital, Failure by Dr. Durrani to inform patient of additional/changed procedure and reason, Failure by UC/West Chester Hospital to disclose additional/changed procedure and reason to patient, Failure by Dr. Durrani to disclose pertinent health information with client, Failure to adhere to professional conduct policy of a physician-** WCH/UCH failed to properly supervise Dr. Durrani, and allowed Dr. Durrani to implant Infuse into Jenny Grimm on 09/30/09, and this failure caused harm to Jenny Grimm. WCH/UCH staff had knowledge of Dr. Durrani using Infuse in Jenny Grimm's case. WCH/UCH failed to address this illegal activity with Dr. Durrani, and this failure caused harm to Jenny Grimm.

21. **Failure by Dr. Durrani at UC /West Chester Hospital to perform accurate and complete postoperative teaching, Failure by Dr. Durrani at UC /West Chester Hospital to properly educate patient regarding diagnoses, Failure by Dr. Durrani and UC/West Chester Health to maintain accurate and/or complete surgical records, Failure by Dr. Durrani to adhere to signed informed consent, Failure by Dr. Durrani and UC/West Chester Health to disclose pertinent health information, Failure to adhere to professional conduct policy of a physician-**Jenny Grimm was not informed regarding the type of surgical procedures, the implantation of Infuse, or Thoracic Level One not being repaired by Dr. Durrani, UC/West Chester Health, or the staff at C.A.S.T. There is no documentation provided by Dr. Durrani or C.A.S.T. showing a pre-operative visit prior to surgery. There is no specification regarding the details discussed with Jenny Grimm. Dr. Durrani and staff at C.A.S.T. failed to properly educate patient regarding diagnoses, treatments, and surgery care.

22. **Failure by Dr. Durrani at UC/West Chester Hospital to adhere to protocols of informed consent, Failure by UC/West Chester Hospital to adhere to protocols of informed consent, Failure by Dr. Durrani to inform patient of additional/changed procedure and reason, Failure by UC/West Chester Hospital to disclose additional/changed procedure and reason to patient, Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information with client, Failure by Dr. Durrani at UC /West Chester Hospital to perform accurate and complete postoperative teaching, Failure by Dr. Durrani at UC /West Chester Hospital to properly educate patient regarding diagnoses, Failure by Dr. Durrani and UC/West Chester Health to maintain accurate and/or complete surgical records, Failure to adhere to professional conduct policy of a physician -** The West Chester surgical consent form signed by Jenny Grimm and Dr. Durrani stated that a C5-6, C6-7, C7-T1 ACDF(Anterior Cervical Discectomy and Fusion) would be performed. Dr. Durrani did not operate on the T1 area. There was also no mention of allograft to be used on the surgical consent form. Dr. Durrani and UC/West Chester Hospital failed to perform accurate and complete preoperative teaching, and also failed to maintain complete and accurate surgical consent forms. Dr. Durrani performed unauthorized procedures, without the consent of Jenny Grimm, which caused harm to her. WCH/UCH failed to properly supervise Dr. Durrani, and allowed Dr. Durrani to not perform on the T1 level, and this failure caused harm to Jenny Grimm.

23. **Failure by Dr. Durrani at UC/West Chester Hospital to adhere to protocols of informed consent, Failure by Dr. Durrani to inform patient of additional/changed procedure and reason, Failure by UC/West Chester Hospital to disclose additional/changed procedure and reason to patient, Failure by Dr. Durrani to disclose pertinent health information with client, Failure by Dr. Durrani at UC /West Chester Hospital to perform accurate and complete postoperative teaching, Failure by Dr. Durrani at UC /West Chester Hospital to properly educate patient regarding diagnoses, Failure by Dr. Durrani and UC/West Chester Health to maintain accurate and/or complete surgical records, Failure by Dr. Durrani and UC/West Chester Health to disclose pertinent health information to Jenny Grimm, Failure by Dr. Durrani and UC/West Chester Health to disclose pertinent health information to, Failure to adhere to professional conduct policy of a physician-On** 10/12/09, Jenny Grimm attended her initial postop consultation with Jamie Moor, PA-C, at CAST. Jamie Moor dictates, "Here for two week post operative visit. She had C5-6, C6-7, and C7-T1 anterior cervical discectomy and fusion, or ACDF." Again, Dr. Durrani did not repair level T1, and did not discuss this with his physician assistant, Jamie Moor, who was evaluating Jenny Grimm. Dr. Durrani failed to disclose pertinent medical information to Jamie Moor or Jenny Grimm, and this failure caused harm to Jenny Grimm.

24. **Failure by UC/West Chester Hospital to orientate Dr. Durrani to hospital policy/procedure, Unnecessary said patient health and safety risk by Dr. Durrani, Unnecessary said patient health and safety risk by UC/West Chester Hospital, Prior knowledge of possible complication and not practicing due diligence Failure by Dr. Durrani at UC /West Chester Hospital to disclose, Health care fraud, Battery, Negligent treatment, Practicing outside the scope of training, education, experience, and Board certifications, Medical negligence, Patient financial loss due to physician ordering of unnecessary, expensive tests and procedures based on inaccurate, fraudulent, and/or exaggeration of diagnoses, Negligent and unnecessary surgery, Failure by Dr. Durrani at UC /West Chester Hospital to inform patient of additional/changed procedure and reason, Grossly negligent surgical techniques, Failure to supervise, Failure by Dr. Durrani at UC /West Chester Hospital to obtain consent, Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information with client, Failure to adhere to professional conduct policy of a physician-On** 01/18/10, at UC/West Chester Hospital, Mrs. Grimm completed surgery performed by Dr. Durrani. The signed hospital surgical consent form lists the procedure to be performed as "Lumbar 3-4 Direct Lumbar Interbody Fusion with Facet Screws". Dr. Durrani lists procedures performed in his OR report as "L3-L4 Lumbar interbody fusion using autograft and allograft, Placement of anterior interbody cage L3-4 (DLIF), Posterior spinal instrumentation L3-4 (facet screws), Posterior spinal fusion using auto and allograft L3-4". Dr. Durrani dictated his OR report on 01/18/10.

25. **Failure by UC/West Chester Hospital to orientate Dr. Durrani to hospital policy/procedure, Prior knowledge of possible complication and not practicing due diligence by Dr. Durrani at UC /West Chester Hospital, Unnecessary said patient health and safety risk by Dr. Durrani, Unnecessary said patient health and safety risk by UC/West Chester Hospital, Failure to disclose by Dr. Durrani at UC /West Chester Hospital , Health care fraud by Dr. Durrani at UC /West Chester Hospital , Battery by Dr. Durrani at UC Hospital/West Chester Hospital , Negligent treatment by Dr. Durrani at UC /West Chester Hospital, Dr. Durrani at UC /West Chester Hospital practicing outside the scope of training, education, experience, and Board certifications, Medical negligence by Dr. Durrani at UC /West Chester Hospital, Patient financial loss due to physician ordering of unnecessary, expensive tests and procedures based on inaccurate, fraudulent, and/or exaggeration of diagnoses,**

Negligent and unnecessary surgery by Dr. Durrani at UC/West Chester Hospital , Failure by Dr. Durrani at UC/West Chester Hospital to inform patient of additional/changed procedure and reason, Grossly negligent surgical techniques by Dr. Durrani at UC/West Chester Hospital, failure to supervise, Failure by Dr. Durrani at UC/West Chester Hospital to obtain consent, Failure by Dr. Durrani to disclose pertinent health information with client, Failure to adhere to professional conduct policy of a physician The Intra-Operative log indicates that Dr. Durrani used rhBMP-2 during this surgery. According to the PMA submitted by Medtronic to the FDA, Infuse was intended for a single level anterior lumbar interbody fusion single performed with all three components in a specific spinal region. The three components that the Infuse device consists of are 1.) A metallic spinal fusion cage (the LT-Cage), 2.) The bone graft substitute, which consists of liquid rhBMP-2, and 3.) A spongy carrier or scaffold for the protein that resides in the fusion cage. With the exception of two non-spinal uses not relevant here, the FDA has not approved any other use of Infuse, including the posterior approach used on Mrs. Grimm by Dr. Durrani. He failed to use the FDA approved cage or spongy carrier, and implemented BMP in a non FDA regulated level of the spine. The off label use of BMP without the expressed or written consent and/or knowledge of Mrs. Grimm is a violation of standards of care, as well as a violation of the manner in which BMP could be used, in accordance with the FDA.

26. WCH/UCH failed to properly supervise Dr. Durrani, and allowed Dr. Durrani to implant rhBMP-2, and this failure caused harm to Jenny Grimm. WCH/UCH staff had knowledge of Dr. Durrani using rhBMP-2 in Jenny Grimm's case. WCH/UCH failed to address this illegal activity with Dr. Durrani, and this failure caused harm to Jenny Grimm.

27. **Failure by Dr. Durrani, CAST, and UC/West Chester Hospital to disclose pertinent information, Failure to perform accurate and complete preoperative teaching** - Dave Rattigan noted to be in the operating room, via UC/West Chester Hospital Intra-Op report. Dr. Durrani did not inform Jenny Grimm that representative, Dave Rattigan, a Medtronic sales representative frequently seen in Infuse cases, would be present during the surgery to observe the surgery.

28. **Inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure to properly educate patient regarding diagnoses, Failure to maintain accurate and complete surgical records, Failure to perform accurate and complete preoperative teaching, Failure to maintain complete and accurate surgical consent forms, Fraudulent, negligent and reckless pre operative work up, Failure to adhere to professional conduct policy of a physician**- Dr. Durrani listed "L3-4 adjacent level degeneration, degenerative disc disease, degenerative spondylolisthesis, and spinal stenosis" as Pre-Operative diagnoses in his Operative Report. According to the 06/25/09 MRI these diagnoses were based from, "There has been fusion performed at L4-5 and L5-S1 levels with pedicle screws. There is significant metallic ferromagnetic artifact at these levels. The disc spaces at L3-4, L4-5, and L5-S1 are difficult to evaluate unfortunately. Clinical correlation necessary. CT myelography may be necessary as well to further evaluate these discs given the metal artifact. However, limited evaluations of these discs do NOT reveal significant canal stenosis or disc protrusions at these levels."

29. **Inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure to properly educate patient regarding diagnoses, Failure to maintain accurate and complete surgical records, Failure to perform accurate and complete preoperative teaching, Failure to maintain complete and accurate surgical consent forms, Fraudulent, negligent and reckless pre operative work up, Failure to adhere to professional conduct policy of a physician** - Jenny Grimm was not informed regarding the implantation of rhBMP-2 by Dr. Durrani or the staff at C.A.S.T. At her preoperative visit (12/08/09), Dr. Durrani stated: "We today discussed the procedure, the risks and benefits, pros

and cons. I feel she understands it." There is no specification regarding the details discussed with Jenny Grimm. Dr. Durrani did not document the modes of teaching and communication used for Jenny Grimm as a learner with mental health diagnoses. Dr. Durrani and staff at C.A.S.T. failed to properly educate patient regarding diagnoses, treatments, and surgery care.

30. **Failure by UC/West Chester Hospital to orientate Dr. Durrani to hospital policy/procedure, Unnecessary said patient health and safety risk by Dr. Durrani, Unnecessary said patient health and safety risk by UC/West Chester Hospital, Prior knowledge of possible complication and not practicing due diligence, Failure by Dr. Durrani at UC /West Chester Hospital to disclose, Health care fraud, Battery, Negligent treatment, Medical negligence, Patient financial loss due to physician ordering of unnecessary, expensive tests and procedures based on inaccurate, fraudulent, and/or exaggeration of diagnoses, Negligent and unnecessary surgery, Failure by Dr. Durrani at UC /West Chester Hospital to inform patient of additional/changed procedure and reason, Grossly negligent surgical techniques, Failure to supervise, Failure by Dr. Durrani at UC /West Chester Hospital to obtain consent, Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information with client, Failure to adhere to professional conduct policy of a physician** - Lumbar Spine xrays ordered by Dr. Durrani and completed at St. Elizabeth Medical Center on 07/31/09 indicate "anterolisthesis of L3 on L4 of 1mm". Dr. Durrani performs surgery on Jenny Grimm on 01/18/10, and lists procedures performed in his OR report as "L3-L4 Lumbar interbody fusion using autograft and allograft, Placement of anterior interbody cage L3-4 (DLIF), Posterior spinal instrumentation L3-4 (facet screws), Posterior spinal fusion using auto and allograft L3-4". During this same surgery, diagnostic lumbar spine xrays taken at the end of surgery still indicate mild persistent anterolisthesis of L3 on L4. The radiology was completed at 10:48am. Jenny Grimm's surgery was completed at 10:54am. A fusion should be done very carefully to ensure that the bone can never slide or slip forwards again thus causing another incidence of anterolisthesis. To ensure this, the surgeon can stabilize the fused vertebrae by fastening it with screws or other hardware. It is apparent that the fusion was not a success before leaving the operating room, yet Dr. Durrani chose to still end surgery, and this decision caused harm to Jenny Grimm.

31. **Inaccurate, fraudulent, and/or exaggeration of diagnoses, Failure to maintain a complete and accurate medical record, Failure to adhere to professional conduct policy of a physician**- On 11/16/10, Jenny Grimm attended a follow up visit with Dr. Durrani at CAST. Dr. Durrani dictates, "We got the xrays done which shows on the standing scoli films, she is about 18cm in positive sagittal balance. Her C2 is way off as compared to the central sacral line. This indicates very severe kyphotic deformity. The predominant pain is actually in her neck at the cervical thoracic junction. I had a long chat with both Jenny and her husband, and I today told them that the only way to treat this severe deformity is to do a cervical thoracic osteotomy and posterior spinal instrumentation from C3 to T6.

32. **Independent Medical Opinion of Surgery Necessity** On 03/15/11, Jenny Grimm attended a follow up consultation with Dr. John Kelly of Neuroscience Associates of Northern Kentucky. Dr. John Kelly dictates, "She underwent cervical fusion C3-6 on 09/30/09 per Dr. Durrani. She then underwent lumbar surgery 01/18/10 per Dr. Durrani. She thought this was a lot harder. She has a lot of right leg pain and weakness. The spasms in the legs have been worse since undergoing surgery....only completed three physical therapy visits, was too painful. Dr. Durrani was proposing a major spinal reconstructive surgery, extending from C3 to T6 and a pedicle-subtraction osteotomy from C7 to T1. After we discussed this on her last visit, she decided not to pursue that.

45. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Jenny Grimm and concealed material facts he had a duty to disclose. UC/West Chester Hospital and CAST concealed material facts they had a duty to disclose. Jenny Grimm was justified in relying on the misrepresentation and did rely proximately, causing harm to Jenny Grimm. Dr. Durrani, UC/West Chester Hospital, and CAST intentionally misled Jenny Grimm. Jenny Grimm had the right to correct information.

46. To a reasonable degree of medical certainty, damages suffered by Jenny Grimm includes aggravation of pre-existing condition; past, present and future pain and suffering; past, present and future loss of enjoyment of life; past, present, and future medical bills, and possible future revision surgery.

47. I will supplement this report based upon the information counsel will provide me including the depositions of the UC/West Chester Hospital, and CAST representatives.

48. My curriculum vitae is attached.

FURTHER AFFIANT SAYETH NAUGHT.

Keith D. Wilkey, M.D.

STATE OF Missouri)

COUNTY OF St. Louis)

SUBSCRIBED, SWORN TO, AND ACKNOWLEDGED, before me, a Notary Public, by Keith D. Wilkey, M.D, on the 24 day of March, 2013.

Susan K. Vietmeier

Notary Public

My Commission. Expires 2-13-15

NOTARY PUBLIC NOTARY SEAL STATE OF MISSOURI

SUSAN K. VIETMEIER
My Commission Expires
February 13, 2015
St. Louis County
Commission #11008831

COMMON PLEAS COURT
HAMILTON COUNTY, OHIO

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Jenny Grimm

CASE NO. A 1506165

VS

Abubakar Atiq Durrani, MD, et al.

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FOREIGN SHERIFF

ON West Chester Hospital, LLC, Serve: GH&R Business Svcs., Inc.

511 Walnut Street, 1900 Fifth Third Center Cincinnati, OH 45202

UC Health, Serve: GH&R Business Svcs., Inc., 511 Walnut Street,

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REQUEST AND INSTRUCTIONS FOR ORDINARY MAIL SERVICE

Jenny Grimm
Plaintiff

-vs-

West Chester Hospital, LLC, et al.
Defendant

INSTRUCTIONS TO THE CLERK

CASE NUMBER: A 1506165

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Matthew J. Hammer
ATTORNEY OF RECORD **(TYPE OR PRINT)**

\s\Matthew J. Hammer
ATTORNEY'S SIGNATURE

DATE